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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MADSON & METCALF
GATEWAY TOWER WEST
SUITE 900
15 WEST SOUTH TEMPLE
SALT LAKE CITY, UT 84101

EXAMINER

NAFF, DAVID M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/075,129

Applicant(s)

TRESKO ET AL

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10 and 12-39 is/are pending in the application.
- 4a) Of the above claim(s) 22-25 and 27-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-10,12-21,26 and 31-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

An amendment of 6/15/05 amended claims 1, 5, 8, 10, 16, 17, 19-21, 31, 32, 36 and 37, added new claims 38 and 39, and canceled claims 4 and 11.

5 Claims in the application are 1-3, 5-10 and 12-39.

Claims 22-25 and 27-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10 9/30/04.

Claims examined on the merits are 1-3, 5-10, 12-21, 26 and 31-39.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

15 Claims 1-3, 5-10, 12-21 and 31-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the 20 time the application was filed, had possession of the claimed invention.

It is not readily apparent where the specification supports the limitations added to claims 1, 8 and 31 by amendment, and for new claims 38 and 39. The page and lines should be pointed where the 25 limitations added by amendment are recited. While Example 6, page 52,

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and Figures 2 and 10-12 are cited as support for new claims 38 and 39, the conditions of claims 38 and 39 are not recited in Example 6, page 52 and the figures, and it is uncertain how claims 38 and 39 were derived from Example 6, page 52 and the figures.

5 **DUPLICATE CLAIMS**

Applicant is advised that should claim 38 be found allowable, claim 39 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, 10 despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

There is no difference in claims 38 and 39, and both depend on claim 8.

15 ***Claim Rejections - 35 USC § 112***

Claims 1-3, 5-10, 12-21, 26 and 31-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20 In line 5 of claim 1 and where required in other claims, "cytoskeletal elements" is uncertain as to meaning and scope. It is uncertain as to material that constitutes cytoskeletal elements.

In claim 31, line 2, "from and individual organism" is confusing. Should "and" be --- an ---?

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In line 2 of claim 36, "or CNS" is confusing since this alternative is no different from the "central nervous system" previously recited. After "system", --- (CNS) --- should be inserted and "or CNS" deleted.

5 Bridging lines 1 and 2 of claims 38 and 39, there is not clear antecedent basis for "the third and greater layers of cells". Previously recited is "three or more layers".

Response to Arguments

10 Applicants urge that pages 23, 35 and 36 of the specification discuss cellular components that make up the cytoskeleton. However, it is not clear from these pages as to cellular components that form the cytoskeleton. Applicant should point out the precise cellular components recited on these pages that form the cytoskeleton.

Claim Rejections - 35 USC § 102

15 Claims 1-3, 5, 8-10, 12, 13, 21 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al.

20 The claims are drawn to a device for propagation of tissue comprising a bioartificial composite comprising a substrate having at least one surface capable of the reception and growth of promoting retention of a cellular preparation and a first layer of adherent cells prepared from the preparation disposed on the surface. The first layer has cytoskeletal elements aligned substantially uniformly with an axis of the substrate, and the composite serves as a template to accept a second layer of cells upon the first layer. The second
25 layer comprises an organized layer oriented in the direction of the

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first layer, and the substrate has at least one surface defined by a critical surface curvature and/or a surface topography having non-uniform grooves substantially aligned with the axis of the substrate, or the curvature and the surface topography (claim 8). Also claimed
5 is a method of preparing the device.

Clark et al disclose topographical guidance of cells using multiple grooved substrata to obtain aligned cells thereon.

The grooved substrata containing aligned cells of Clark et al is a device that is the same as the device presently claimed. The cells
10 on the substrata of Clark et al are inherently in the form of a layer having cytoskeletal elements aligned uniformly with a axis of the substrate, and the layer is inherently capable of serving as a template for a second layer of cells as claimed. The substrata of Clark et al inherently has a critical surface curvature and/or
15 topography. The conditions of dependent claims are also inherently part of the substrata containing cells of Clark et al. The method of preparing the device of Clark et al is the same as required by claim
21.

Response to Arguments

20 Applicants urge that claims 1 and 8 have been amended to require "non-uniform grooves substantially aligned with the axis of the substrate". However, claim 1 recites "and/or" and does not require this limitation. As to claim 8, "non-uniform grooves" are inherent in grooves of Clark et al since it is inherent in Clark et al that there
25 will be some variation in the grooves. The procedure of making the

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grooves will result in all grooves not being exactly the same. The claims do not require a certain amount of non-uniformity, and encompass a small amount of non-uniformity that can occur in Clark et al. The grooves of Clark et al are inherently substantially aligned with an axis of the substrate depending on where the substrate is considered to have the axis. The claims do not limit the location of axis of the substrate.

Claim Rejections - 35 USC § 103

Claims 1-3, 5-10, 12-19, 21, 26 and 31-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton et al (5,858,721) in view of Clark et al and Ricci et al (6,419,491 B1) and Curtis et al (4,832,759).

The invention is described above. Additionally, claim 26 requires a method for preparation of tissue by incubating the substrate containing a layer of cells.

Naughton et al disclose (paragraph bridging cols 2 and 3, and col 3, lines 9-25) growing stromal cells on a support matrix to produce a stromal matrix and then growing cells derived from a desired tissue on the stromal matrix to produce components of tissue analogous to counter parts found *in vivo*. Multiple cell layers are provided (col 6, line 36).

Clark et al is described above.

Ricci et al disclose (col 4, lines 36-49) a dental implant having a collar section containing an ordered microgeometric repetitive surface pattern in the form or a multiplicity of alternating ridges

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and grooves that define a guide for preferential promotion of the rate, orientation and direction of growth colonies of cells.

5 Curtis et al disclose (col 1, lines 26-37) locating a plurality of cells in a predetermined spatial disposition relative to each other on a solid substrate by providing a generally planar surface with discontinuities defining cell-adhesion enhanced and/or cell-adhesion orienting zones. The discontinuities can be grooves and ridges (col 2, lines 5-10). The cells can be cells having cytoskeletons (col 2, lines 28-37).

10 It would have been obvious provide the support matrix of Naughton et al with features such as grooves and/or ridges to provide topographical cell guidance as suggested by Clark et al and to promote orientation and direction of cell growth as suggested by Ricci et al and to provide cells in a predetermined spatial disposition as
15 suggested by Curtis et al. Naughton et al disclose multiple layers being obtained, and the stromal cells form a first layer and the tissue-specific cells form a second layer, and the stromal layer inherently acts as a template for the second layer. The conditions of dependent claims would have been matters of obvious choice in view of
20 the disclosures of the references. Naughton et al disclose (col 3, lines 22-26, and col 8, lines 48-52) treating the matrix with materials to enhance cell attachment as in claims 6 and 7, and these materials will inherently minimize non-specific protein binding. A substrate with a roughness or curvature as in claim 2 or 3 and non-
25 planar shape as in claim 5 would have been obvious from roughness and

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curvature of the substrates of Clark et al, Ricci et al and Curtis et al. A filamentous substrate as in claim 16, cylindrical substrate as in claims 17 and 18 and an axially aligned surface topography as in claim 19 would have been merely a matter of individual preference for a particular form and/or shape of the substrate. The support of Naughton et al can have cell attachment molecules as in claim 19. The method of claim 21 is suggested by Clark et al, and producing tissue as in claim 26 would have been obvious from the tissue producing method of Naughton et al. Cell sources and forms of substrate as in claims 31-37 would have been obvious from cells and substrates from disclosed by the references.

Response to Arguments

As above, applicants refer to the amendment to claims 1 and 8 requiring "non-uniform grooves substantially aligned with the axis of the substrate". However, for reasons set forth above, this amendment does not distinguish over Clark et al.

Claim Rejections - 35 USC § 103

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-3, 5-10, 12-19, 21, 26 and 31-39 above, and further in view of Vandenburg (4,940,853).

The claim requires applying force to the layer of cells or substrate to promote morphological rearrangement.

Vandenburg discloses that it is known to apply forces to align cells when producing tissue (col 1, lines 20-25).

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When forming tissue by the method of Naughton et al and using a support matrix as set forth above, it would have been obvious to apply force to align cells in tissue produced as suggested by Vandenburg.

Response to Arguments

5 Comments above also apply to the traverse of this rejection since applicants rely on the type of arguments responded to above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE**
10 **FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

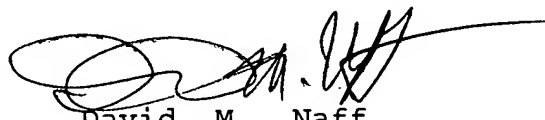
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date
15 of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,
20 however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be
25 reached on Monday-Friday 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 751-273-8300.

5 Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For
10 more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

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DMN
8/22/05